

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-19-0102; NOP-19-05]

RIN 0581-AD93

National Organic Program; National List of Allowed and Prohibited Substances -

Crops and Handling from October 2019 NOSB

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule amends the National List of Allowed and Prohibited Substances (National List) section of the United States Department of Agriculture's (USDA) organic regulations to implement recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB). This rule allows the following substances for organic production: potassium hypochlorite to treat irrigation water used in organic crop production and fatty alcohols for sucker control in organic tobacco production. This rule also removes the listing for dairy cultures, as it is redundant with an existing listing.

DATES: This rule is effective on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Jared Clark, Standards Division, National Organic Program. Telephone: (202) 720-3252

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Secretary established the Agricultural Marketing Service's (AMS) National Organic Program (NOP) and the USDA organic regulations (65 FR 80547, December 21, 2000). Within the USDA organic regulations (7 CFR part

205) is the National List of Allowed and Prohibited Substances (or "National List"). The National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic crop and livestock production. It also identifies the nonorganic substances that may be used in or on processed organic products.

AMS is finalizing three amendments to the National List in accordance with the procedures detailed in the Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6501–6524). OFPA establishes what may be included on the National List and the procedures that the USDA must follow to amend the National List (7 U.S.C. 6517). OFPA also describes the NOSB's responsibilities in proposing amendments to the National List, including the criteria for evaluating amendments to the National List (7 U.S.C. 6518).

To remain on the National List, substances must be: (1) reviewed every five years by the NOSB, a 15-member federal advisory committee; and (2) renewed by the Secretary (7 U.S.C. 6517(e)). This action of NOSB review and USDA renewal is commonly referred to as the "sunset review" or "sunset process." AMS published information about this process in the *Federal Register* on September 16, 2013 (78 FR 56811). The sunset date (i.e., the date by which the Secretary must renew a substance for the listing to remain valid on the National List) for each substance is included in the NOP Handbook (document NOP 5611). The first sunset date for the substances added to the National List in this final rule will be five years from the effective date in the DATES section of this final rule above.

This final rule adds potassium hypochlorite and fatty alcohols to the National List.

Once the final rule becomes effective, producers of organic crops will be allowed to use these substances in organic production. The permitted use of each substance is discussed in detail in "Overview of Amendments." This final rule also removes the listing for dairy

cultures in 7 CFR 205.605(a). This removal will not affect the allowance of dairy cultures in organic production and organic products as they will continue to be allowed under the microorganisms listing in 7 CFR 205.605(a).

II. Overview of Amendments

This rule adds potassium hypochlorite and fatty alcohols to the National List for use in organic crop production. This rule also removes dairy cultures from the National List, but their allowance is continued through the microorganisms listing. Additional background on the petitions and the NOSB's review of the substances may be found in the proposed rule (86 FR 15800, March 25, 2021).

During a 60-day comment period that closed on May 24, 2021, AMS received six comments on the proposed rule. See below for a discussion of the comments received and AMS's responses to comments. Comments can be viewed through Regulations.gov. Use the search area on the homepage at https://www.regulations.gov to enter a keyword, title, or docket ID (the docket folder for this rule is AMS-NOP-19-0102).

Potassium Hypochlorite (§ 205.601)

The final rule amends the National List to add potassium hypochlorite to 7 CFR 205.601 as a synthetic, chlorine-based sanitizer allowed for use in organic crop production. This amendment allows use of potassium hypochlorite in organic crop production for the purposes of cleaning irrigation equipment and treating irrigation water.

AMS is finalizing this amendment to the National List, as recommended by the NOSB, to provide organic farmers an additional tool for treating irrigation water and cleaning irrigation equipment, which the U.S. Food and Drug Administration (FDA) requires to promote food safety (21 CFR part 112 subpart E). Potassium hypochlorite provides an alternative to sodium hypochlorite, which may cause sodium accumulation in soil with repeated use (sodium hypochlorite is allowed for use at 7 CFR 205.601(a)(2)(iv)).

Following receipt of a petition in November 2018,¹ the NOSB recommended adding potassium hypochlorite to the National List in October 2019.² In their evaluation of potassium hypochlorite, the NOSB considered comments from the public and the petition itself. The NOSB discussed the petition to amend the National List in subcommittee calls and at its public meeting in October 2019.³

After their evaluation, the NOSB concluded that adding potassium hypochlorite to the National List is consistent with evaluation criteria in the OFPA (7 U.S.C. 6518(m)). The NOSB found that use of potassium hypochlorite for irrigation water treatment and cleaning of irrigation equipment would be compatible with organic crop production, providing additional use benefits over sodium hypochlorite (e.g., no accumulation of sodium in soil). The NOSB noted that potassium hypochlorite also provides an additional tool for organic farmers to meet the requirements of the FDA Food Safety Modernization Act (FSMA, Pub. L. 111-353).

AMS review

AMS concludes that the addition of potassium hypochlorite to the National List is consistent with the three requirements of the OFPA (7 U.S.C. 6517(c)(1)(A)). First, when used as labeled for irrigation purposes, the substance is not harmful to human health or the environment. Second, it is necessary because of the absence of wholly natural substitute products. And third, it is consistent with organic farming. This amendment follows the NOSB recommendation according to the procedures established in the OFPA (7 U.S.C. 6517(d)).

¹ "Petition to Add Synthetic Substance to National List," Potassium Hypochlorite Solution, November 2018, https://www.ams.usda.gov/sites/default/files/media/PotassiumHypochloritePetition.pdf.

² "Formal Recommendation from National Organic Standards Board (NOSB) to the National Organic Program (NOP)," Potassium Hypochlorite, October 25, 2019, https://www.ams.usda.gov/sites/default/files/media/CSPotassiumHypochlorite.pdf.

³ Written and oral public comments submitted for the Fall 2019 NOSB Meeting are available at https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-pittsburgh-pa.

Comments received and AMS's response

AMS received two comments in response to the proposed listing of potassium hypochlorite. The subjects of these comments and responses from AMS are covered in this section. AMS is changing the final listing of potassium hypochlorite in response to one of these comments and to better clarify its use in organic crop production.

Unintentional use allowance. One commenter expressed concern that the annotation, as proposed, would allow additional uses outside those petitioned and recommended by the NOSB. Some additional uses identified are boot sanitizers, tool sanitation, cleaning of planting trays and pots, and reduction of biofilms.

AMS did not intend for additional allowances beyond managing irrigation water and equipment. To address this, AMS is finalizing the addition of potassium hypochlorite as the NOSB originally proposed. The finalized annotation will read "for use in water for irrigation purposes."

Not eligible for addition. One commenter asserted that potassium hypochlorite does not meet the criteria outlined in OFPA for the addition of a synthetic substance to the National List. The comment states the addition of potassium hypochlorite poses adverse impacts on human health and the environment, is not essential in organic production, and is incompatible with organic production.

NOSB must consider the above criteria when evaluating substances for inclusion on the National List (7 U.S.C. 6518(m)). NOSB considered and discussed these criteria during their Fall 2019 meeting⁴ and in their formal recommendation for rulemaking.⁵
AMS must also consider similar criteria when adding synthetic substances to the National List, which AMS discussed in the proposed rule preceding this action (86 FR 15800).

⁴ "National Organic Standards Board Meeting – Pittsburgh, PA," USDA, Agricultural Marketing Service, https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-pittsburgh-pa.

⁵ "Formal Recommendation from National Organic Standards Board (NOSB) to the National Organic Program (NOP)," Potassium Hypochlorite, October 25, 2019, https://www.ams.usda.gov/sites/default/files/media/CSPotassiumHypochlorite.pdf.

Both reviews by NOSB and AMS determined potassium hypochlorite meets the criteria for National List addition as described in the sections NOSB REVIEW AND RECOMMENDATION and AMS REVIEW.

Fatty Alcohols (§ 205.601)

This final rule amends the National List to add fatty alcohols (C_6 , C_8 , C_{10} , and/or C_{12}) to § 205.601(k) as a synthetic substance allowed for use as sucker (secondary stems) control in organic tobacco production. The fatty alcohol designations C_6 , C_8 , C_{10} , and C_{12} correspond to 1-hexanol, 1-octanol, 1-decanol, and 1-dodecanol.

Fatty alcohols can be derived from fats or oils (most commonly coconut oil, palm kernel oil, lard, tallow, rapeseed oil, soybean oil, and corn oil) or from petroleum products. Applying fatty alcohols to tobacco plants, generally in the presence of a surfactant, selectively kills or inhibits sucker growth. Fatty alcohols are necessary to provide a safer and effective method of de-suckering tobacco plants. Without an allowance for fatty alcohols, farmers would need to rely on manual sucker removal, which would potentially expose workers to nicotine poisoning. Removal of suckers facilitates growth of the harvestable leaves, reduces pest pressure, and increases crop yield.

NOSB review and recommendation

Following receipt of a petition in December 2018,⁷ the NOSB recommended adding fatty alcohols to the National List in October 2019.⁸ In the NOSB's evaluation of fatty alcohols, the NOSB considered comments from the public, a previously

⁶ "Green Tobacco Sickness," U.S. Department of Labor, Occupational Safety and Health Administration, https://www.osha.gov/green-tobacco-sickness.

⁷ "Fatty Alcohols for use on Organic Tobacco Crops," National List Petition or Petition Update, USDA, Agricultural Marketing Service,

https://www.ams.usda.gov/sites/default/files/media/RevisedPetitionNaturalFattyAlcoholsforUseonOrganic TobaccoCrops.pdf.

⁸ "Formal Recommendation from National Organic Standards Board (NOSB) to the National Organic Program (NOP)," Fatty Alcohols, October 25, 2019, https://www.ams.usda.gov/sites/default/files/media/CSFattyAlcoholsFinalRec_0.pdf.

commissioned technical report,⁹ and the petition itself. The NOSB discussed this petition in subcommittee calls and at its public meeting in October 2019.¹⁰

After their evaluation, the NOSB concluded that adding fatty alcohols to the National List is consistent with the evaluation criteria in the OFPA (7 U.S.C. 6518(m)). The NOSB found that use of fatty alcohols for sucker removal is essential for organic crop production, providing a tool to effectively inhibit sucker growth without exposing workers to the potential health impacts associated with manual desuckering. Additionally, the NOSB acknowledged fatty alcohols readily break down in the environment.

AMS review

AMS concluded that the addition of fatty alcohols to the National List is consistent with the requirements in the OFPA (7 U.S.C. 6517(c)). First, when used as labeled for desuckering purposes, the substance is not harmful to human health or the environment. Second, it is necessary because of the absence of wholly natural substitute products. And third, due to its natural source material and being easily biodegradable, it is consistent with organic farming. This amendment follows the NOSB recommendation according to the procedures established in the OFPA (7 U.S.C. 6517(d)).

Comments received and AMS's response

AMS received four comments in response to the proposed listing of fatty alcohols for sucker control. The subjects of these comments and responses from AMS are covered in this section.

Inconsistent with organic production. One commenter opposed the addition of fatty alcohols to the National List. The comment stated that fatty alcohols pose health and environmental hazards, are not needed, and are inconsistent with organic production.

⁹ "Fatty Alcohols (Octanol and Decanol)," Crops, Technical Report, August 1, 2016, https://www.ams.usda.gov/sites/default/files/media/FattyAlcohols020217.pdf.

¹⁰ Written and oral public comments submitted for the Fall 2019 NOSB meeting are available at https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-pittsburgh-pa.

In support of these claims, the comment cited several sections of the technical report on fatty alcohols. The comment stated that longer-chain fatty alcohols resist hydrolysis and may bioaccumulate and are toxic to aquatic organisms. The comment also quoted sections of the technical report referring to potential sublethal effects on Lepidopteran species. The comment offered an alternative to fatty alcohols indoleacetic acid—for desuckering. Lastly, the comment asserted that fatty alcohols do not fall into any OFPA categories at 7 U.S.C. 6517(c)(1)(B)(i).

AMS believes the information cited from the technical report was either misunderstood or misquoted. First, while the technical report does state that longer fatty alcohol chains are not expected to hydrolyze readily, the report defines these as having a carbon chain longer than 12.11 As this allowance is limited to fatty alcohols of carbon chain length 6, 8, 10, and 12, accumulation is not expected to occur. Second, the report does state the potential for sublethal effects on Lepidopteran species. Dodecanol (C₁₂) fatty alcohol) is used in U.S. Environmental Protection Agency (EPA) registered products as a mating disruption pheromone. 12 However, concentrations of dodecanol in mating disruption products (approximately 30%) are much higher than those in products for sucker control (less than 1%).¹³ Given the much lower concentration of fatty alcohols, limited use of fatty alcohols for sucker control, and quick decomposition of these substances, AMS does not expect this use of fatty alcohols will have a measurable effect on Lepidopterans.

The comment also stated fatty alcohols do not fit into an OFPA category at 7 U.S.C. 6517(c)(1)(B)(i). AMS acknowledges that the NOSB did not identify an OFPA

^{11 &}quot;Fatty Alcohols (Octanol and Decanol)," Crops, Technical Report, August 1, 2016, Technical Report, lines 303-305, August 1, 2016,

https://www.ams.usda.gov/sites/default/files/media/FattyAlcohols020217.pdf.

¹² U.S. Environmental Protection Agency, February 3, 2014,

https://www3.epa.gov/pesticides/chem_search/ppls/053575-00006-20140203.pdf.

¹³ "Fatty Alcohols (Octanol and Decanol)," Crops, Technical Report, August 1, 2016, Technical Report, table 1, August 1, 2016, https://www.ams.usda.gov/sites/default/files/media/FattyAlcohols020217.pdf.

category for these substances. AMS views the limited use allowance of fatty alcohols to fall under the OFPA category of "production aid," as identified in the petition.

Desuckering is necessary plant maintenance in tobacco production to facilitate growth of the harvestable leaves, reduce pest pressure, and increase crop yield. This narrow use allowance of fatty alcohols aids in the production of organic tobacco by allowing farmers to perform this necessary maintenance task without risk to worker health.

Finally, the comment offered the alternative substance, indoleacetic acid (listed as indole-3-acetic acid by the EPA). While indoleacetic acid may be naturally occurring, it appears the common method of production is a synthetic process that would not be permitted in organic production.

General support. Two comments supported the addition of fatty alcohols to the National List. One commenter certifies many tobacco farms and stated many of their tobacco operations indicated that fatty alcohols are critical to the success of their organic farms. Another certifying agent commented they also certify several tobacco farmers, one of which already requested approval of fatty alcohols for sucker control.

In addition to mentioning the support of certified operations, these comments also indicate the proposed listing is clear and likely will not cause confusion. An additional comment offered general support for the review process and an acknowledgement of the NOSB's robust deliberative process of this substance.

AMS appreciates public engagement in the rulemaking process and agrees with the general support noted above, which mirrors the recommendation by the NOSB. AMS is moving forward with adding this substance to the National List as proposed.

*Dairy Cultures (§ 205.605)

This final rule amends the National List to remove dairy cultures from § 205.605(a) as a nonsynthetic substance allowed for use in organic processed products. This removal is not expected to affect any currently allowed or future products. Any

cultures allowed under this listing will continue to be allowed under the listing for microorganisms at § 205.605(a).

NOSB review and recommendation

Following the sunset review of dairy cultures, the NOSB recommended removing dairy cultures from the National List. As described in the BACKGROUND section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

In its recommendation, the NOSB stated the listing for dairy cultures was no longer needed, concluding that the allowance of microorganisms at § 205.605(a) provides an alternative to the dairy cultures listing. This recommendation acknowledged the widespread use of dairy cultures and NOSB meeting participants' comments, which confirmed that the removal of the dairy cultures listing will not affect their allowance. Comments received and AMS's response

Opposition. One commenter opposed the removal of dairy cultures from the National List, citing three reasons to maintain the listing. First, the commenter stated the removal of dairy cultures may cause consumer confusion. The comment stated there is potential for reduced transparency without a clear connection between "dairy cultures" as listed on product labels and the "microorganisms" listing on the National List. Second, the comment identified the unique application of dairy cultures. While the comment acknowledges dairy cultures are a subset of microorganisms, it also stated a preference to maintain the listing to assist any future annotation. Finally, the comment questioned whether sunset review is the appropriate time for this removal. The comment stated this action should be the result of a petition or a separate recommendation track, not the product of a sunset review.

AMS does not believe removing the "dairy cultures" listing will result in widespread confusion or reduced transparency. While AMS acknowledges a preference to have ingredient declarations exactly match the National List allowance, many substances on the National List are known by multiple names, not all of which are listed. If widespread confusion occurs, AMS would prefer to address the confusion through education rather than expanding the National List to include all possible ingredient names.

AMS acknowledges the desire to keep dairy cultures for sake of flexibility. Regardless of whether dairy cultures remain on the list, any recommended annotation would need to come from the NOSB and go through the rulemaking process. As such, there is no added flexibility or resource savings in maintaining the listing; the process to add dairy cultures with an annotation is similar in time and resources to only adding the annotation. Lastly, AMS does not believe this action is inappropriate for the sunset process, which is intended to regularly evaluate National List substances against the criteria in OFPA at 7 U.S.C. 6518(m). One of these criteria is "alternatives to using the substance in terms of practices or other available materials." The NOSB's sunset review determined that there are other available materials (microorganisms), rendering this listing unnecessary.

Several other comments were neutral (neither in support of nor in opposition to the removal of the dairy cultures listing). One comment requested further examination of the allowed fermentation processes of microorganisms in general.

AMS appreciates public engagement in the rulemaking process. AMS is moving forward with removing this listing from the National List as proposed.

III. Related Documents

AMS published notices in the Federal Register announcing the Spring 2019 NOSB Meeting (83 FR 60373, November 26, 2018) and announcing the Fall 2019

NOSB meeting (84 FR 23522). These notices invited public comments on the NOSB recommendations addressed in this final rule. The AMS proposed rule that preceded this final rule was published on March 25, 2021 (86 FR 15800).

IV. Statutory and Regulatory Authority

OFPA authorizes the Secretary to make amendments to the National List based on recommendations developed by the NOSB. The OFPA authorizes the NOSB to develop recommendations for submission to the Secretary to amend the National List and establish a process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List (7 U.S.C. 6518 (k) and (n)). Section 205.607 of the USDA organic regulations permits any person to petition to add or remove a substance from the National List and directs petitioners to obtain the petition procedures from USDA (7 CFR 205.607). The current petition procedures published in the Federal Register (81 FR 12680, March 10, 2016) for amending the National List can be accessed through the NOP Handbook on the NOP website at https://www.ams.usda.gov/rules-regulations/organic/handbook.

A. Executive Order 12866 and Regulatory Flexibility Act

This proposed rule does not meet the criteria of a significant regulatory action under Executive Order 12866 as supplemented by Executive Order 13563. Therefore, the Office of Management and Budget (OMB) has not reviewed this rule under those Orders.

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to the action.

Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an

analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The Small Business Administration (SBA) sets size criteria for each industry described in the North American Industry Classification System (NAICS) to delineate which operations qualify as small businesses. ¹⁴ The SBA classifies small agricultural producers that engage in crop and animal production as those with average annual receipts of less than \$1,000,000 (13 CFR 121.201). Handlers are involved in a broad spectrum of food production activities and fall into various categories in the NAICS Food Manufacturing sector. The small business thresholds for food manufacturing operations are based on the number of employees and range from 500 to 1,250 employees, depending on the specific type of manufacturing. Certifying agents fall under the NAICS subsector "all other professional, scientific, and technical services." For this category, the small business threshold is average annual receipts of less than \$16.5 million.

Producers. AMS has considered the economic impact of this final rulemaking on small agricultural entities. Data collected by the USDA National Agricultural Statistics Service (NASS) and the NOP indicate most of the certified organic production operations in the United States would be considered small entities. According to the 2017 Census of Agriculture, 16,585 organic farms in the United States reported sales of organic products and total farmgate sales more than \$9.9 billion. Based on that data, organic sales average just under \$600,000 per farm. Assuming a normal distribution of producers, we expect that most of these producers would fall under the \$1,000,000 sales threshold to qualify as a small business.

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¹⁴ "Table of Small Business Size Standards Matched to North American Industry Classification System Codes," U.S. Small Business Administration, August 19, 2019, https://www.naics.com/wp-content/uploads/2017/10/SBA_Size_Standards_Table.pdf.

¹⁵ "2019 Organic Survey," 2017 Census of Agriculture, USDA National Agricultural Statistics Service, table 1,

 $https://www.nass.usda.gov/Publications/AgCensus/2017/Online_Resources/Organics/ORGANICS.pdf.$

Handlers. According to the NOP's Organic Integrity Database (OID), there are 10,971 U.S.-based organic handlers that are certified under the USDA organic regulations. ¹⁶ The Organic Trade Association's 2020 Organic Industry Survey has information about employment trends among organic manufacturers. The reported data are stratified into three groups by the number of employees per company: fewer than 5; 5 to 49; and 50 plus. These data are representative of the organic manufacturing sector and the lower bound (50) of the range for the larger manufacturers is significantly smaller than the SBA's small business thresholds (500 to 1,250). Therefore, AMS expects that most organic handlers would qualify as small businesses.

Certifying agents. The SBA defines "all other professional, scientific, and technical services," which include certifying agents, as those having annual receipts of less than \$16,500,000 (13 CFR 121.201). There are currently 76 USDA-accredited certifying agents, based on a query of the OID database, who provide organic certification services to producers and handlers. While many certifying agents are small entities that would be affected by this final rule, we do not expect that these certifying agents would incur significant costs as a result of this action as certifying agents already must comply with the current regulations (e.g., maintaining certification records for organic operations).

AMS does not expect the economic impact on entities affected by this rule to be significant. The effect of this final rule will allow the use of two additional substances in organic crop production and remove a redundant listing for one substance in organic handling. Adding two substances to the National List will increase regulatory flexibility and provide small entities with more options to use in day-to-day operations. Removal of the substance in organic handling will have no impact as its use will continue to be allowed under another National List allowance.

¹⁶ Organic Integrity Database, USDA, accessed October 27, 2021, https://organic.ams.usda.gov/Integrity.

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This final rule is not intended to have a retroactive effect. Accordingly, to prevent duplicative regulation, states and local jurisdictions are preempted under OFPA from creating programs of accreditation for private persons or state officials who want to become certifying agents of organic farms or handling operations. A governing state official would have to apply to the USDA to be accredited as a certifying agent, as described in the OFPA (7 U.S.C. 6514(b)). States are also preempted from creating certification programs to certify organic farms or handling operations unless the state programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA (7 U.S.C. 6503–6507).

Pursuant to the OFPA (7 U.S.C. 6507(b)(2)), a state organic certification program that has been approved by the Secretary may, under certain circumstances, contain additional requirements for the production and handling of agricultural products organically produced in the state and for the certification of organic farm and handling operations located within the state. Such additional requirements must: (a) further the purposes of OFPA; (b) not be inconsistent with OFPA; (c) not be discriminatory toward agricultural commodities organically produced in other States; and (d) not be effective until approved by the Secretary.

In addition, pursuant to 7 U.S.C. 6519(c)(6), this final rule does not supersede or alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601–624), the Poultry Products Inspection Act (21 U.S.C. 451–471), or the Egg Products Inspection Act (21 U.S.C. 1031–1056) concerning meat, poultry, and egg products, respectively, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority

of the Administrator of the EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

C. Paperwork Reduction Act

No additional collection or recordkeeping requirements are imposed on the public by this final rule. Accordingly, Office of Management and Budget (OMB) clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

D. Executive Order 13175

This final rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on: (1) policies that have tribal implication, including regulation, legislative comments, or proposed legislation; and (2) other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the federal government and Indian Tribes.

AMS has assessed the impact of this final rule on Indian Tribes and determined that this rule would not have tribal implications that require consultation under Executive Order 13175. AMS hosts a quarterly teleconference with tribal leaders when matters of mutual interest regarding the marketing of agricultural products are discussed.

Information about the proposed changes to the regulations are shared during these quarterly calls, and tribal leaders have the opportunity to comment on the proposed changes.

E. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

F. General Notice of Public Rulemaking

This final rule reflects recommendations submitted by the NOSB to the Secretary to add two substances to the National List and remove one substance from the National List.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agricultural commodities, Agriculture,
Animals, Archives and records, Fees, Imports, Labeling, Livestock, Organically
produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia,
Soil conservation.

For the reasons set forth in the preamble, AMS amends 7 CFR part 205 as follows:

PART 205—NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501–6524.

- 2. Amend § 205.601 by:
- a. Revising paragraph (a)(2)(iv);
- b. Adding paragraph (a)(2)(v);
- c. Revising paragraph (k);

The revisions and addition read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

* * * * *

- (a) * * *
- (2) * * *
- (iv) Potassium hypochlorite for use in water for irrigation purposes.
- (v) Sodium hypochlorite.

* * * * *

- (k) As plant growth regulators.
- (1) Ethylene gas for regulation of pineapple flowering.
- (2) Fatty alcohols (C6, C8, C10, and/or C12) for sucker control in organic tobacco production.

* * * * *

§ 205.605 [Amended]

3. In § 205.605, amend paragraph (a) by removing the words "Dairy cultures".

Erin Morris,

Associate Administrator,

Agricultural Marketing Service.

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